4083. Misbranding of dextro-amphetamine sulfate tablets, methyltestosterone tablets, and tablets containing a mixture of sulfadiazine and sulfathiazole. U. S. v. Times Square Drug and Albert Kline. Pleas of guilty. Fine of $150 against each defendant. (F. D. C. No. 34334. Sample Nos. 36096–L, 36204–L, 36227–L.)

INFORMATION FILED: February 20, 1953, Northern District of Ohio, against Times Square Drug, a partnership, Cleveland, Ohio, and Albert Kline, a pharmacist for the partnership.

NATURE OF CHARGE: On or about April 10, 1952, while a number of *tablets containing a mixture of sulfadiazine and sulfathiazole* were being held for sale at Times Square Drug after shipment in interstate commerce, the defendants caused various quantities of the tablets to be repacked and dispensed without a prescription, which acts resulted in the repackaged tablets being misbranded as follows: Section 502 (b) (1) and (2), the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the label of the repackaged tablets failed to bear the common or usual name of each active ingredient of the tablets; and, Section 502 (f) (1) and (2), the labeling of the repackaged tablets failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of the users.

On or about May 15 and June 11, 1952, while a number of *dextro-amphetamine sulfate tablets* and *methyltestosterone tablets* were being held for sale at Times Square Drug after shipment in interstate commerce, the defendants caused quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drugs being misbranded.

DISPOSITION: March 13, 1953. Pleas of guilty having been entered, the court fined each defendant $150.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4084. Misbranding of homeopathic drugs. U. S. v. Various Quantities, etc. (F. D. C. No. 34103. Sample Nos. 64024–L to 64054–L, incl.)

LIBEL FILED: November 4, 1952, Western District of Washington.

ALLEGED SHIPMENT: On various dates, the Kansas City Homeopathic Pharmacy shipped from Kansas City, Mo., a number of drugs in tablet form in 5-pound packages. In addition, there were shipped by another firm, on July 25, 1952, and on other dates, from St. Louis, Mo., a number of drugs in powder form in labeled bulk containers. There was shipped also from a point outside of the State of Washington, on an unknown date, a quantity of a drug in powder form in an unlabeled bulk container.

PRODUCT: Various quantities of various homeopathic drugs in tablet form, some in 5-pound bulk packages in which they were shipped, and some in bottles of 400 tablets each into which the tablets were repacked from the bulk packages at destination; various quantities of drugs in powder form in labeled bulk containers and in retail-sized containers used in repacking such drugs; and a

quantity of a drug in powder form, some of which was in bulk in an unlabeled container and some of which had been repacked into retail-sized containers.

All of the drugs were in possession of L. W. Andrus, at Chehalis, Wash., together with a number of booklets entitled "Schuessler's Biochemic Remedies," a number of mimeographed sheets entitled "ABC Health Club Remedial Biochemistry," and a number of leaflets entitled "The most effective program." The booklets had been shipped to L. W. Andrus on September 15, 1952, and the mimeographed sheets and leaflets were prepared by or for L. W. Andrus and contained statements relating to the drugs in tablet form.

LABEL, IN PART: (Drugs in tablet form in bulk packages) "Homeopathic Calcarea Fluorica 3X Calcium Fluoride [or "Calcarea Phosphorica 3X Calcium Phosphate," "Calcarea Sulph. 3X Calcarea Sulphate," "Ferrum Phosphoricum 3X Iron Phospate," "Kali Muriaticum 3X Potassium Chloridum," "Kali Phosphoricum 3X Potassium Phosphate," "Kali Sulphuricum 3X Potassium Sulphate," "Magnesium Phosphorica 3X Magnesium Phosphate," "Natrum Muriaticum 3X Chloride of Sodium-Salt," "Natrum Phosphoricum 3X Sodium Phosphate," "Natrum Sulphuricum 3X Sodium Sulphate," and "Silicea 3X Silica"]."

(Drugs in tablet form repackaged into bottles) "Biochemic Remedies * * * 400 Tabs. 3X * * * L. W. Andrus, Oroville, Wash." and respectively identified as "Calcium Fluoride 1," "Calcium Phosphate 2," "Calcium Sulphate 3," "Iron Phosphate 4," "Potassium Chloride 5," "Potassium Phosphate 6," "Potassium Sulphate 7," "Magnesium Phosphate 8," "Sodium Chloride 9," "Sodium Phosphate 10," "Sodium Sulphate 11," and "Silica 12."

(Drugs in powder form in bulk containers) "Sodium Phosphate," "Sodium Sulphate," and "Calcium Phosphate."

(Drugs in powder form—repackaged) "Sodium (10 crude) Phosphate," "Sodium crude (11) Sulphate," and "Calcium (2 crude) Phosphate."

(Drug in powder form repacked from unlabeled container into retail-sized containers) "ABCO."

NATURE OF CHARGE: Drugs in tablet form (in bulk packages and as repacked into bottles). Misbranding, Section 503 (b) (4), the articles were drugs intended for use by man, which, because of the collateral measures necessary for their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription." Further misbranding, Section 502 (a), the labeling of the articles in tablet form, namely, the accompanying booklet entitled "Schuessler's Biochemic Remedies," contained statements which were false and misleading in that the articles were not effective for the purposes stated and implied and were not capable of fulfilling the promises of benefit made for them. The statements represented and suggested—

(a) that all of the articles were effective to eliminate the cause of disease and restore health, and that they were effective for acute and chronic conditions;

(b) that the calcium fluoride was effective for the alleviation of affections of the respiratory organs and difficult expectoration, ulceration of mouth and throat, caries and necrosis with boring pains and heat in parts, induration threatening suppuration, chronic suppuration of middle ear, ailments arising from relaxed condition of the elastic fibers of the connective tissue or lymphatics, ailments caused by dilation of the blood vessels, such as simple hemorrhoids, blood tumors, prolapsus of the womb, swellings, indurated en-

largements, varicose and enlarged veins, hardened glands in female breast, glandular tumors, relaxed vulva, malnutrition of bones, acute indigestion from fatigue and brain fag, and much flatulence;

(c) that the calcium phosphate was effective for disturbances resulting from faulty nutrition or improper assimilation, such as simple anemia; for children who are peevish, flabby, have cold extremities, and feeble digestion; for delayed nutrition; for deficient development of children; for emaciation without apparent cause, as evidenced by spinal weakness, spinal curvature, "ruchiatis," craniotabes, and hydrocephalus; for suppuration of bones; to aid the union of fractured bones and promote the development of teeth; for the expectant mother, preserving her teeth and insuring proper development of her teeth; for individuals having green, slimy, hot, sputtering undigested stools, with fetid flatus; and to aid in chronic, wasting diseases;

(d) that the calcarea sulphate was effective to promote healing of simple skin eruptions, for the suppurative stage of skin and eruptive diseases; abscesses, boils, pustules, ulcers, burns or scalds, milk crust, ulcerated tooth; discharge of matter from ear, expectoration of pus, chronic catarrhal conditions with foul secretions, quinsy, sore throat, ulceration of glands, ulcers on legs, rattling coughs after colds, burning-itching of soles of feet, mucous discharges yellow, thick, and lumpy, and pimples and pustules on the face;

(e) that the iron phosphate was effective for the alleviation of the fever, congestion, inflammation, and pain occurring during the initial stage of minor acute ailments, such as colds, throat irritations, hard, dry, tickling cough after colds, flushed face, quick, full pulse, hot dry skin, thirst, marked prostration, pain and redness of the parts, first state of inflammation of any organ or tissue, simple anemia, muscular pains, vomiting of undigested food, incontinence, enuresis, with weak sphincter, epistaxis, bright red hemorrhages from any orifice, and congestive headaches;

(f) that the potassium chloride was effective for alleviation of catarrhal conditions, especially of the respiratory passages, thick white or grayish secretions from any of the mucous membranes, white or gray coating of the tongue, for the second stage of inflammatory diseases, subacute inflammatory states, fibrinous exudations and glandular swellings, skin affections of any part of the body, skin eruptions with small vesicles, containing yellowish secretions, leucorrhea, with mucus, sometimes yellowish, muscular pains with indigestion caused by fatty, rich food, and for coughs following colds;

(g) that the potassium phosphate was effective for the relief of minor disturbances of the nervous system, neurasthenic conditions in general prostration, irritability, restlessness, nervousness, sleeplessness, nervous headaches, neuralgic pains, lancinating pains in the nerves, enuresis, incontinence of urine, nervous dispepsia, dizziness, vertigo from nervous exhaustion, offensive, carrion-like diarrhea, predisposition to epistaxis in children, tongue as if spread with liquid (dark) mustard, offensive breath, humming and buzzing in the ears, very yellowish urine, and yellow expectoration;

(h) that the potassium sulfate was effective for the alleviation of inflammatory and catarrhal conditions with thin, sticky, watery, or slimy yellowish secretions with a yellow slimy deposit on tongue, coughing spells with oppressed breathing, hard, hoarse, or croupy cough with rattling of mucus in the chest, for skin diseases having a sticky, yellowish secretion and peeling off of the epidermis, for bronchitis, with yellow, slimy, or thin, watery expectoration, dyspepsia, catarrh of the stomach and bowels, with characteristic yellowish slimy coating of the tongue, catarrhal condition of bowels, ulceration or sud-

den suppression or retrocession of eruptions, and shifting, wandering pains in extremities;

(i) that the magnesium phosphate was effective as an antispasmodic, for the relief of spasmodic, muscular, and neuralgic pains, neuralgic headaches, cramps, facial neuralgia, pains in the head, face, teeth, stomach, and abdomen which are relieved by warmth, spasmodic retention of urine, spasmodic palpitation and cardiac pain while sitting, functional cardiac affections with liver enlargement, pains that are lightning-like, boring, shooting, change their location frequently; acute, loud, spasmodic coughs; and diseases having their origin in the nerve cells or in the terminal bulbs of the nerves, in the muscular tissues, or in the muscles themselves;

(j) that the chloride of sodium-salt was effective to alleviate the acute symptoms in colds, throat and bronchial irritations, hay fever with profuse, thin, watery vomiting, hypersecretion of the watery elements of the body with simultaneous lack in activity in some other portion of the mucous membrane, muscles weak and stiff, great weakness and weariness, coldness of legs with congestion in head, chest, and stomach, emaciation most notable in neck, great liability to take cold, dry mucous membranes, diseases of the respiratory organs, with thin, watery expectoration, headache, toothache, face ache, stomach ache, etc., where there is either salivation or hypersecretion of tears or vomiting of water and mucus, constipation, intermitting or remitting fever, catarrhal affections of mucous membranes with secretion of transparent, watery, frothy mucus, small watery blisters, breaking or leaving a thin crust, enuresis, diarrhea, transparent, glossy, slim stools, conjunctivitis with discharge of tears and clear mucus, loss of smell and taste, and leucorrhea with watery, smarting, or clear, starch-like discharges;

(k) that the sodium phosphate was effective for the relief of minor ailments characterized by gastric and excessive acidity of the stomach, sour eructations and taste, sour vomiting, chronic dyspepsia, flatulence with sour risings, heartburn, burning in stomach after meals, indigestion, sour smelling diarrhea, colic and spasms, yellow, creamy coating of the tongue, such as in diarrhea, acid stomach, muscular pains due to acidity, moist, thick, golden yellow, or creamy coating at the back of roof of mouth and tongue, ague with described coating of tongue, and eyes discharging a yellow, creamy water;

(l) that the sodium sulfate was effective for the alleviation of bilious and periodic headaches, colds, colic, diarrhea and disordered stomach with bilious symptoms, dark-coated tongue, bitter taste with excess of bile, hepatic derangements, enlargement of the liver, skin affections with bilious vomiting, yellowish skin, and moist, yellowish scales, every spring return of skin affections, and vomiting of pregnancy, with symptoms usually worse in the evening;

(m) that the silica was effective for the alleviation of minor skin ailments attended by slow suppuration, disposition for boils, styes, and similar eruptions, offensive secretion caused by catarrh, thick, yellow, lumpy discharges, offensive foot sweat, fetid perspiration of feet, hands, and axillae, scrofulous, rachitic children, large head and open fontanelles and sutures, distended abdomen, slow in walking; lymphatic, sanguineous temperament; small foreign bodies under the skin or in the larynx, suppurative inflammation of the connective tissue, constipation with ineffectual straining, and imperfect assimilation and consequent defective nutrition. The drugs in tablet form were alleged to be misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

Further misbranding, Section 502 (a), the labeling of the articles in tablet form, namely, the mimeographed sheet, entitled "ABC Health Club" and the leaflets entitled "The most effective program," contained statements which were false and misleading since the articles were not effective for the purposes represented. The statements represented and suggested that the calcium fluoride, calcium phosphate, calcium sulfate, and iron phosphate were effective for disorders of the bones, teeth, connective tissue, and muscles; that the potassium chloride, potassium phosphate, potassium sulfate, and magnesium phosphate were effective for disorders of the brain, nerves, organic tissue, and liver; that the chloride of sodium-salt, sodium phosphate, sodium sulfate, and silica were effective for disorders of the blood, lymph, serums, and secretions; that the calcium phosphate and sodium phosphate were effective to reduce cellular activity and remedy calcium deficiency; and that the magnesium phosphate was effective to relieve pain or nervousness and to bring sleep. The articles were misbranded in these respects while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the articles in tablet form failed to bear adequate directions for use for the purposes for which they were intended, namely, the conditions for which they were offered in lectures delivered by L. W. Andrus at Chehalis, Wash., on September 4 and 18, 1952, and in a conversation with Food and Drug Inspector Rowland F. Walter, in September 1952, as follows:

Calcium fluoride—to increase rate of child's growth, to fluidify the blood, and for insomnia; calcium phosphate—to build new cells, for cancer and pneumonia, to slow the heart, and to enrich the blood; calcium sulfate—for affections of the bones, to reduce the rate of a child's growth, hemorrhage, liver weakness, and inactivity of the liver; iron phosphate—to enrich the blood; potassium chloride—to build nerve cells, for tuberculosis, to knock out fever, to fluidify the blood, to cure pneumonia, to thin the blood, to enrich the blood, and for insomnia; potassium phosphate—to fluidify the blood, for asthma, liver weakness, and inactivity of the liver; potassium sulfate—to enable one to grow up and mature emotionally, to cure pneumonia, for fever and to thin the blood, for liver weakness and inactivity of the liver, and for insomnia; magnesium phosphate—to build sensory nerves, for eyes, hearing, smell, and taste, to cure pneumonia, and for insomnia and nervousness; sodium chloride—for cancer, to fluidify the blood, to cure pneumonia, to thin the blood, to enrich the blood, and for insomnia; sodium phosphate—for liver weakness and inactivity of the liver; sodium sulfate—for insomnia; and silica—for tuberculosis.

Further misbranding, Section 502 (i) (3), the articles in tablet form were offered for sale under the names of other drugs, as follows: (calcium fluoride)—vitamin B; (calcium phosphate)—vitamin B complex; (calcium sulfate)—vitamin K; (iron phosphate)—vitamin C; (potassium chloride)—vitamin F; (potassium phosphate)—vitamin D; (potassium sulfate, sodium sulfate, and silica)—vitamins, the identities of which are not yet known; (magnesium phosphate)—vitamin E; (chloride of sodium-salt)—vitamin G or B_2; and (sodium phosphate)—vitamin A.

The articles in tablet form were alleged to be misbranded under Sections 502 (f) (1) and 502 (i) (3), as indicated above, while held for sale after shipment in interstate commerce.

Sodium phosphate and sodium sulfate—drugs in powder form (in bulk containers and as repacked). Misbranding, Section 502 (a), the labels of the

articles contained statements which represented and suggested that the sodium phosphate was an adequate and effective treatment for gas, heartburn, and other distress, and that the sodium sulfate would effect a direct liver reaction to remove stagnant bile, which statements were false and misleading since the sodium phosphate was not an adequate and effective treatment for the conditions stated and the sodium sulfate would not effect a direct liver reaction to remove stagnant bile; and, Section 502 (f) (2), the labels of the articles failed to bear such adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe methods or duration of administration, in such manner and form, as are necessary for the protection of users since their labeling did not bear warnings against use in case of nausea, vomiting, abdominal pain, or other symptom of appendicitis, nor against frequent or continued use which may cause dependency upon laxatives to move the bowels. The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

Calcium phosphate—drug in powder form (in bulk container and as repacked). Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to reveal the purpose for which the article was intended. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

Drug in powder form repacked from unlabeled container into retail-sized containers and labeled "ABCO." Misbranding, Section 502 (a), the label statements "for revulsive hand, foot and abdominal hot applications. Neck, spine and congestive areas need ABCO sprinkled on a cold compress" were false and misleading since the article was not effective for the purposes stated and implied. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: June 17, 1953. L. W. Andrus, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the drugs be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare, and that the above-mentioned booklets, mimeographed sheets, and leaflets be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4085. Misbranding of pentobarbital sodium capsules and sulfathiazole tablets and conspiracy to violate the laws of the United States. U. S. v. Harry W. Wilson (Wilson Drug Co.), and Seth R. Medley. Pleas of guilty. Defendant Wilson fined $640 and sentenced to 6 months in jail; jail sentence suspended and defendant placed on probation for 1 year. Defendant Medley fined $114. (F. D. C. No. 33715. Sample Nos. 85336–K, 85345–K, 85346–K, 85350–K, 85351–K, 19318–L, 19319–L, 19332–L, 19340–L, 19348–L, 19356–L, 19364–L, 19367–L, 19368–L.)

INFORMATION FILED: December 16, 1952, Western District of Wisconsin, against Harry W. Wilson, trading as the Wilson Drug Co., Spooner, Wis., and Seth R. Medley, a physician.

ALLEGED VIOLATION: On or about November 6 and December 1 and 18, 1950, and January 5 and 24, March 4, 20, and 30, April 12, and May 2, 1951, while a number of *pentobarbital sodium capsules* and *sulfathiazole tablets* were

*See also Nos. 4083, 4084.